

**REMARKS**

Claims 1, 3 and 5 through 8 are pending in the application.

Claims 1 and 5 have been amended to emphasize that the inventive methods form drug, food or cosmetic films by applying a drug, food or cosmetic coating onto a carrier material, thereby contaminating the carrier material with drug, food or cosmetic contaminants. Support for this amendment can be found in the Application-as-filed, for example on Page 4, lines 5 through 20.

Claim 1 has also been amended to emphasize advantageous inventive processes that supply the carrier material on a reel. Support for this amendment can be found in the Application-as-filed, for example on Page 4, lines 5 through 20.

Claim 6 has been amended to emphasize that the active ingredients, adjuvants, flavors or fragrances within the drug, food or cosmetic coating penetrates into and contaminates the carrier material. Support for this amendment can be found in the Application-as-filed, for example on Page 3, lines 1 through 7.

Claim 8 has been amended to reflect advantageous embodiments in which the thermal treatment consists of an infra red heat treatment. Support for this amendment can be found in the Application-as-filed, for example on Page 5, lines 8 through 18.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

*The Claimed Invention is Patentable*

*in Light of the Art of Record*

Claims 1, 3 and 5 through 7 stand rejected over United States Patent No. 4,562,020 (“US 020”) to Hijiya et al. in view of United States Patent No. 4,079,106 (“US 106”) to Goldsworthy et al.; United States Publication No. 2003/0228196 to Satchwell and United States Patent No. 5,112,220 (“US 220”) to Wimberger et al.<sup>1</sup> Claims 1 and 8 stand rejected over the foregoing references and further in light of United States Patent No. 5,804,357 (“US 357”) to Yamanouchi et al.

It may be useful to briefly consider the invention before addressing the merits of the rejection.

Drugs, foods and cosmetics (hereinafter referred to as “consumables”) are known for consumption in film-forms, and various production processes are known for their manufacture. In general, film-form consumables are manufactured on fully automated production lines by forming thin sheets of an active-ingredient film on a carrier material. Such processes may be either continuous, as evidenced in cited US 020, or as discrete batches, as reflected in Claim 1 as-amended.

Batch operations are attractive, as the materials used to form the active-ingredient film may be readily changed. In forming consumable films via a batch operation, the active-ingredient containing film is typically peeled off of the carrier material and the separated carrier material is taken up onto a reel. Unfortunately, the active-ingredient (as well as any additional adjuvants or other coating compounds) can penetrate into the carrier material due to diffusion. The carrier material is then contaminated by these substances, up to their respective degree of saturation.

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<sup>1</sup> Applicants respectfully submit that United States Publication No. 2003/0228196 (“US 196”) has matured into United States Patent No. 6,840,712 (“US 712”). Accordingly, remarks directed to US 712 are intended to distinguish US 196, as well.

Consequently, once the active ingredient containing film has been peeled off the carrier material, the contaminated carrier material can not be used again, since it is loaded to a non-specified degree with diffused active ingredients and the like (hereinafter referred to as "contaminants," as noted above). The required disposal such contaminated carrier material presents both an economic and environmental challenge.

Surprisingly, Applicants have found that drug, food and cosmetic contaminants can be evaporated from carrier materials using simple thermal treatments performed at moderate temperatures and dwell times, such as at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes, and the evaporated contaminants can then be permanently disposed of by feeding the evaporated contaminants to a thermal after-burner using controlled air circulation, as recited in the claimed invention.

Altogether unexpectedly, the foregoing decontamination does not significantly detrimentally impact the physical properties of the carrier material. Hence the decontaminated carrier material, also referred to as neutralized carrier material, may then be reused as a carrier within the active-ingredient film forming process, as further recited in Claim 1.

In particularly advantageous embodiments, the thermal treatment consists of an infra-red heat treatment, as recited in newly added Claim 8.

Applicants respectfully reiterate that the cited references do not teach or suggest the claimed invention.

Specifically, the full combination of references does not teach or suggest the removal of drug, food or cosmetic contaminants from a carrier material used to form an active-ingredient-containing drug, food or cosmetic film, as recited in the claims as-amended.

Nor does the full combination of references teach or suggest such removal of drug, food or cosmetic contaminants from a carrier material supplied on a reel, as further recited in Claim 1 as-amended.

US 020 is merely directed to the use of a filled glucan to form self-supporting films having sufficient strength. (Col. 2, lines 22 – 31). To form the self-supporting film, an aqueous glucan solution is cast onto an endless corona-treated belt, dried and released. (Col. 2, lines 16 – 23). US 020 generically notes that the glucan film “may be, if necessary” admixed with any of generic ingredients. (Col. 3, lines 25 – 35). US 020 dries its films using warm or hot air. (Col. 3, lines 42 – 45; Col. 4, lines 27 – 30; Col. 5, lines 30 – 35; *inter alia* ).

As correctly noted by the Examiner in the prior Office Action, US 020 does not teach or suggest decontamination.

In fact, US 020 does not teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as recited in Claim 1 as-amended. Applicants further respectfully submit that the urgings within the outstanding Office Action on Page 7, third paragraph, concerning any contamination within US 020 is purely conjecture. Furthermore, the carrier of US 020 would not have “necessarily” been contaminated, as US 020 does not require additional ingredients beyond its glucan.

US 020 thus can not teach or suggest the recited decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all of the undesired substances from the carrier material.

And US 020, solely directed to endless belts, most certainly does not teach or suggest the inventive decontamination of carrier material supplied on a reel, as further recited in Claim 1 as-amended.

US 020, repeatedly noting hot air drying of its glucan film, likewise can not teach or suggest such decontamination via thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended.

Applicants thus respectfully reiterate that the claimed invention is patentable in light of US 020, considered either alone or in combination with the remaining art of record.

Applicants respectfully reiterate that the secondary references do not cure the deficiencies in US 020.

US 106 is directed to the continuous fabrication of polyurethane foam insulation. (Col. 1, lines 55 – 60). Liquid/molten polymer is applied to three dimensional filaments disposed on the surface of a belt which has been coated with a wax or an equivalent release agent. ( Col. 2, lines 25 - 28 and 44 – 45). After curing sufficiently, the foamed material is “cut” from the belt. (Col. 2, lines 39 – 41). After cutting the cured/dried material from the belt, the belt is “cleaned” and subsequently re-coated with a wax or release agent. (Col. 2, lines 43 – 47) Suitable cleaning methods include mechanical cleaning and solvent cleaning. (Col. 2, line 44). As correctly noted by the Examiner, US 106 teaches that the belt is “automatically returned” to the initial portion of the machine; therefore the process is “continuous.” (Col. 2, lines 43 – 47)

US 106, directed to foam insulation, does not teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as recited in Claim 1 as-amended. Applicants further respectfully reiterate that the required wax or release agent of US 106 would prevent penetration of foam contaminants into the continuous belt.

US 106 thus can not teach or suggest the inventive decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all the drug, food or

cosmetic contaminants from the carrier material, as further recited in Claim 1. US 106 instead merely generically notes that a number of cleaning options are available.

Nor does US 106, generically noting “cleaning,” teach or suggest feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation.

And US 106 most certainly does not teach or suggest the inventive decontamination of carrier material supplied on a reel, as additionally recited in Claim 1 as-amended. As correctly noted by the Examiner on Page 4, first sentence, US 106 is instead directed to the formation of foam on a continuous belt.

US 106 likewise fails to teach or suggest such decontamination via thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 106, considered either alone or in combination with the remaining art of record.

US 712 is directed to methods of cleaning contaminated flowable solid media, such as contaminated soil and the like, via one or more screw conveyors. (Col. 3, lines 19 – 32). Hot, inert gas is injected through a plurality of openings in a screw conveyor contained within a vacuum housing. (Col. 3, lines 43 – 65). The temperatures within the screw conveyors range from 235 °C up to 649 °C. (Col. 11, lines 35 -46). In the highest temperature “pyrolysis” zone, an organic binder may be added to encapsulate contaminants. (Col. 3, lines 39 – 40 and Col. 7, lines 23 – 27). In the alternative, the volatiles are removed from the vacuum housing are introduced into a forced air cooler or refrigeration system where the volatiles are “cooled and condensed.” (Col. 9, lines 63 – 65).

Applicants respectfully make of record that US 712, directed to a heated screw conveyors to treat soil, is not pertinent in any form or fashion to the formation of active-ingredient-containing films.

US 712 simply can not teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as recited in Claim 1 as-amended.

Nor does US 712, teaching either encapsulation or condensation of volatile contaminants, teach or suggest feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation.

And US 712, teaching temperatures of up to 649 °C, most certainly does not teach or suggest the recited decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all of the drug, food or cosmetic contaminants from the carrier material. US 712 instead suggests that far more elevated temperatures would be required.

US 712, solely directed to soil “carried” by screw conveyors, further can not teach or suggest the inventive decontamination of carrier material supplied on a reel, as further recited in Claim 1 as-amended.

US 712 likewise fails to teach or suggest such decontamination via a thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended. US 712 instead requires hot gas emitted via a screw conveyor. Applicants respectfully submit that to modify US 712 so as to avoid its heated screw conveyors would render US 712 unfit for its intended purpose.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 712, considered either alone or in combination with the remaining art of record.

Applicants respectfully reiterate that US 220 is directed to air floatation driers for graphic arts that use solvent-laden air as a combustion medium in generating high drying temperatures. (Col. 1, lines 14 – 19 and Col. 2, lines 45 - 51). US 220's driers are intended to dry ink on graphic arts media using a raw gas burner. (Col. 6, lines 1 – 6 and 20 - 23). US 220 notes that a “typical” graphic arts dryer may have temperatures of up to 500 °F (i.e. 260 °C). (Col. 6, lines 6 – 7). US 220 goes on to note that one factor of its operation is its “high temperature combustion of 600 F to 2200 °F.” (Col. 6, lines 25 – 30). As correctly noted by the Examiner, US 220 is altogether silent as to treatment duration.

US 220, directed to the drying of ink on graphic arts media, does not teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as recited in Claim 1 as-amended. Applicants respectfully submit that the media of US 220 is self-supporting, and there is no teaching or suggestion of a carrier material, much less a contaminated carrier material.

US 220, teaching temperatures of up to 500 °F, thus can not teach or suggest the inventive decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all the drug, food or cosmetic contaminants from the carrier material, as further recited in Claim 1. In contrast to the urgings of the outstanding Office Action on Page 4, last partial paragraph, 176 °F (80 °C) is not within the “envisioned” temperature range of US 220. Applicants further respectfully submit that there would have been absolutely no motivation to have lowered the elevated temperatures taught in US 220. US 220, considered as a whole, instead emphasizes its “high internal drying temperatures” and its “high temperature combustion,” and thus clearly teaches away from the moderate decontamination temperature of Claim 1. Furthermore, US 220 makes no teaching or suggestion that a temperature range used to dry solvent from graphic arts media would be effective in removing drug, food or cosmetic contaminants from a carrier material.

Nor does US 220, merely disclosing solvent/air combustion, teach or suggest feeding food, drug or cosmetic contaminants to a thermal after-burning using controlled air circulation.

And US 220, directed to self-supporting graphic arts media, most certainly does not teach or suggest the inventive decontamination of carrier material supplied on a reel, as additionally reflected in Claim 1 as-amended.

US 220, solely directed to air drying, likewise fails to teach or suggest such decontamination via a thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended.

Applicants respectfully reiterate that the claimed invention is not taught or suggested by US 220, considered either alone or in combination with the remaining art of record.

Applicants respectfully submit that there would have been absolutely no motivation to have combined the foregoing references. US 020 is directed to filled glucan. US 106 is directed to foam insulation. US 196 is directed to screw conveyors to decontaminate soil. US 220 is directed to graphic arts dryers using ink solvent as a combustion medium. These are extraordinarily different fields of endeavor and problems solved.

Applicants further respectfully submit that the arts of foam insulation, screw conveyors and graphic arts are incredibly divergent, and that any teachings even arguably present within such references could not reasonably have been expected to be successful in the claimed invention.

However, even if the foregoing references were combined (which Applicants did not do), the claimed invention would not have resulted.

The combination simply does not teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as recited in Claim 1 as-amended. US 020 does not teach or suggest contamination. US 106 is directed to polyurethane foam. US 220, directed to the drying of self-supporting graphic arts media, does not even have a carrier material, much less contaminants diffusing therein. US 712 merely moves soil using heated screw conveyors, and in no way teaches or suggests processes in which contaminants diffuse into a carrier material.

The combination thus can not teach or suggest the inventive decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all the drug, food or cosmetic contaminants from the carrier material, as further recited in Claim 1. US 020 does not teach or suggest decontamination. US 106 generically suggests a number of cleaning processes for its continuous belt. Considered in their entirety, US 220 and US 712 both teach far more elevated temperatures. US 220 teaches temperatures of up to 500 °F, while US 712 teaches temperatures up to 649 °C.

Nor does the combination teach or suggest feeding food, drug or cosmetic contaminants to a thermal after-burning using controlled air circulation. As noted above, US 020 is silent as to contamination. US 106 merely notes that its continuous belt may be cleaned by any of a number of generic processes. US 220 teaches solvent/air combustion. US 712 teaches either an organic binder to encapsulate volatile contaminants or, alternatively, condensation of contaminants.

And the combination most certainly does not teach or suggest the inventive decontamination and reuse of carrier material supplied on a reel, as additionally recited in Claim 1 as-amended. US 020 and US 106 are directed to continuous belts as supports. US 220 is directed to self-supporting media that has no carrier. US 712 is merely directed to soil “carried” via screw conveyor.

And the combination, altogether silent as to heat treatments other than hot air/gas, can not teach or suggest such thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended.

Applicants thus respectfully reiterate that the claimed invention is patentable in light of US 020; US 106; US 712 and US 220, considered either alone or in any combination.

Claim 8 is similarly patentable in further light of US 357.

US 357 is directed to fine diameter latex particles for use in silver halide photographic light-sensitive material. (Col. 1, line 12 – 24). The methods and materials of US 357 allow the formation of high contrast images at pHs of less than 11.0 with only a small amount of developer supplementation. (Col. 1, lines 25 – 30 and Col. 4, lines 36 - 44). Polyester film may be used as the substrate for the silver halide photographic material, and the films preferably subjected to a surface-treatment to increase adhesion of the photographic layer to the film. (Col. 28, lines 23 – 26). US 357 teaches that the polyester film may be heated prior to such surface-treatment by heating with an infrared heater and heating via contact with a hot roll. (Col. 29, lines 39 – 46).

US 357, expressly teaching the heating of film via infrared heating and a hot roll, can not teach or suggest the inventive decontamination via thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended.

Nor does US 357, directed to fine diameter latex particles , teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as further recited in Claim 8 as-amended.

US 357 thus can not teach or suggest the recited decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all of the undesired substances from the carrier material.

And US 357 most certainly does not teach or suggest the inventive decontamination of carrier material supplied on a reel, as additionally recited in Claim 8 as-amended.

As noted above, US 020, US 106, US 712 and US 220 do not cure the foregoing deficiencies.

There likewise would have been no motivation to have combined the foregoing references. Applicants respectfully submit that there would have been absolutely no motivation to have combined the foregoing references. US 020 is directed to a filled glucan. US 106 is directed to foam insulation. US 196 is directed to screw conveyors to decontaminate soil. US 220 is directed to graphic arts dryers using ink solvent as a combustion medium. US 357 is directed to fine diameter latex particles. Again, these are extraordinarily different fields of endeavor and problems solved.

However, even if US 020, US 106, US 712, US 220 and US 357 were combined (which Applicants did not do), the claimed invention would not have resulted.

The combination simply does not teach or suggest the inventive decontamination via thermal treatment consisting of an infra red heat treatment, as recited in Claim 8 as-amended. US 357 instead expressly teaches the heating of film via infrared heating and a hot roll. The remaining references do not cure this deficiency, as discussed above.

Nor does the combination teach or suggest that coating a drug, food or cosmetic coating onto a carrier material would result in the contamination of the carrier material with drug, food or cosmetic contaminants, as further recited in Claim 8 as-amended.

The combination further can not teach or suggest the recited decontamination performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all of the undesired substances from the carrier material.

And the combination most certainly does not teach or suggest the inventive decontamination of carrier material supplied on a reel, as additionally recited in Claim 8 as-amended.

Applicants thus respectfully submit that Claim 8 is likewise patentable in light of US 020; US 106; US 712, US 220, and US 357 considered either alone or in any combination.

### CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 3 and 5 through 8 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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